Page 1 of 18

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	) ) )
Plaintiffs,	) ) ) C.A. No. 06-286 (GMS)
V.	) )
BARR LABORATORIES, INC.	, ) )
Defendant.	) )
	)

## NOTICE OF SUBPOENAS

PLEASE TAKE NOTICE that defendant Barr Laboratories, Inc. has served the attached subpoenas upon GlaxoSmithKline, Schering Corporation and Schering Plough Corporation.

PLEASE TAKE FURTHER NOTICE that on August 3, 2006, copies of Barr Laboratories Inc.'s Notice of Rule 45 Subpoena (Records Only) were served upon the following counsel of record in the manner indicated:

### **BY FEDERAL EXPRESS**

Steven J. Balick, Esquire John G. Day, Esquire Tiffany Geyer Lydon, Esquire **ASHBY & GEDDES** 222 Delaware Avenue, 17th Floor Wilmington, DE 19801

DB02:5452961.1 063987.1003 Paul H. Berghoff, Esquire
Joshua R. Rich, Esquire
Jeremy E. Noe, Esquire
Paul S. Tully, Ph.D.
MCDONNELL BOEHNEN HULBERT
& BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (#1088) Karen L. Pascale (#2903) Karen E. Keller (#4489) The Brandywine Building 1000 West Street, 17th Floor Wilmington, Delaware 19899 (302) 571-6600 kkeller@ycst.com

### OF COUNSEL:

George C. Lombardi Maureen L. Rurka WINSTON & STRAWN LLP 35 West Wacker Drive Chicago, Illinois 60601 (312) 558-5600

Attorneys for Defendant Barr Laboratories, Inc.

Dated: August 3, 2006

AO 88 (Rev. 1/94) Subpoena in a Civil Case

# Issued by the UNITED STATES DISTRICT COURT

Page 3 of 18

EASTERN DISTRICT OF PENNSYLVANIA

AVENTIS PHARMACEUTICALS, INC. and	
SANOFI-AVENTIS US LLC	
**	SUBPOENA IN A CIVIL CASE
V.	
BARR LABORATORIES, INC.	CASE NUMBER: C.A. No. 06-286 (GMS) (For a case pending in the District of Delaware)
TO:	
Custodian of Records	
GlaxoSmithKline	
One Franklin Plaza	
Philadelphia, PA 19101	
-	istrict Court at the place, date, and time specified below to testify in the
above case. PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME
VOLLAGE COMMANIDED to appear at the place date and	time specified below to testify at the taking of a deposition in the above
case.	time specified below to testify at the taking of a deposition in the above
PLACE OF DEPOSITION	DATE AND TIME
YOU ARE COMMANDED to produce and permit inspection time specified below (list documents or objects):	n and copying of the following documents or objects at the place, date, and
See Exhibit A attached	
PLACE	DATE AND TIME August 18, 2006
GlaxoSmithKline	10:00 a.m.
One Franklin Plaza	
Philadelphia, PA 19101	
YOU ARE COMMANDED to permit inspection of the follo	
PREMISES	DATE AND TIME
	of a deposition shall designate one or more officers, directors, or managing agents,
of Civil Procedure, 30(b)(6).	r each person designated, the matters on which the person will testify. Federal Rule
ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFEN	DANT) DATE August 3, 2006
gula mano	August 3, 2000
Julia M. Mano, Attorney for Defendant Barr Laboratories, In ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER	
Julia M. Mano, Winston & Strawn LLP, 35 W. Wacker Dr.,	Chicago, IL 60601 (312) 558-5600
(See Rule 45, Federal Rules of Civil Procedure, Parts C &	D on Reverse)

<sup>1</sup> If action is pending in district other than district of issuance, state district under case number.

AO 88 (Rev. 1/94) Subpoena in a Civil Case			
	PROOF OF	SERVICE	
DATE	PLACE		
SERVED			
SERVED ON (PRINT NAME)	MANNE	R OF SERVICE	
SERVED BY (PRINT NAME)		TITLE	
	DECLARATION	N OF SERVER	
I declare under penalty of perju	ry under the laws of the United	States of America that the foregoing information contained in	_
the Proof of Service is true and co	rrect.		
Executed on			
Executed on	DATE	SIGNATURE OF SERVER	
		ADDRESS OF SERVER	

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

- (c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.
- (1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.
- (2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.
- (B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.
- (3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
  - (i) fails to allow reasonable time for compliance;
  - (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in

person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

- (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
  - (iv) subjects a person to undue burden.
  - (B) If a subpoena
- (i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
- (ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
- (iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

#### (d) DUTIES IN RESPONDING TO SUBPOENA.

- (1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.
- (2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

#### EXHIBIT A

## DEFINITIONS WITH RESPECT TO ITEMS SUBPOENAED

The terms used in the following list of items subpoenaed shall be construed as follows:

- "GlaxoSmithKline" means "GlaxoSmithKline" and/or "GlaxoSmithKline PLC" and/or "SmithKline Beecham Corp." and all of its predecessors, successors, parents, subsidiaries, affiliates, present and former directors, officers, employees, agents, representatives, investigators, attorneys, and all other persons acting or purporting to act for or on behalf of GlaxoSmithKline involved in or related to the manufacture and/or sale of Flonase® and/or Beconase AQ®.
  - "Documents" means documents as defined in Fed. R. Civ. P. 34(a)(1). B.
- "Relating to" means to consist of, refer to, reflect, or be in any way legally, C., logically, or factually connected with the matter discussed.
- When a document or thing that "concerns" or "concerning" any given matter is D. sought, the request encompasses any document or thing, as the case may be, containing, constituting, evidencing, referring to, discussing, or prepared in connection with the matter.

#### INSTRUCTIONS

- Each document or thing or group of documents or things produced in response to the subpoena shall indicate the item number of the subpoena to which it is responsive.
- For purposes of this subpoena, a document or thing is deemed to be in your control if you have the right to secure the document or thing or a copy thereof from another person or entity having actual possession of the document or thing.
- C. If a claim of privilege is asserted with respect to a document responsive to any of these requests, the following information shall be provided with respect to each such document:
  - the type of document, e.g., letter or memorandum; (a)
  - the general subject matter of the document; (b)
  - the date of the document; and (c)
  - such other information as is sufficient to identify the document for a (d) subpoena duces tecum, including, where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other.

#### ITEMS SUBPOENAED

- Documents, whether public or non-public, sufficient to identify, describe, or show the formulation for Flonase® nasal spray (NDA No. 020121) as of the approval date of NDA No. 020121, October 19, 1994, and any and all modifications to the Flonase® formulation from October 19, 1994 to the present and the date of any such modification.
- Documents, whether public or non-public, sufficient to identify, describe, or show the size of the solid particles of fluticasone propionate medicament contained in Flonase® nasal spray from October 19, 1994 to the present.
- Documents, whether public or non-public, concerning, referring to or relating to any and all nasal deposition pattern testing performed using Flonase® including but not limited to the date of and results of such nasal deposition pattern testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all spray plume geometry testing performed using Flonase® nasal spray including but not limited to the date of and results of such spray plume geometry testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all viscosity testing performed using Flonase® nasal spray including but not limited to the date of and results of such viscosity testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all testing performed to determine retention of the fluticasone propionate medicament contained in Flonase® nasal spray on the mucosal surfaces of the nasal cavity including but not limited to the location at which the medicament was retained and the amount and duration of retention.
  - Twenty samples from the most recent available batches of Flonase® nasal spray. 7.
- Twenty samples from batches of Flonase® nasal spray based on the formulation of Flonase® nasal spray in effect on or before July 3, 1995.
- Documents, whether public or non-public, sufficient to identify, describe, or show 9. the formulation for Beconase AQ® nasal spray (NDA No. 019389) as of the approval date of NDA No. 019389, July 27, 1987, and any and all modifications to the Beconase AQ® formulation from June 27, 1987 to the present and the date of any such modification.
- Documents, whether public or non-public, sufficient to identify, describe, or show 10. the size of the solid particles of beclomethasone dipropionate monohydrate medicament contained in Beconase AQ® nasal spray from July 27, 1987 to the present.
- Documents, whether public or non-public, concerning, referring to or relating to 11. any and all nasal deposition pattern testing performed using Beconase AQ® including but not limited to the date of and results of such nasal deposition pattern testing.

- Documents, whether public or non-public, concerning, referring to or relating to any and all spray plume geometry testing performed using Beconase AQ® nasal spray including but not limited to the date of and results of such spray plume geometry testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all viscosity testing performed using Beconase AQ® nasal spray including but not limited to the date of and results of such viscosity testing.
- Documents, whether public or non-public, concerning, referring to or relating to 14. any and all testing performed to determine retention of the beclomethasone dipropionate monohydrate medicament contained in Beconase AQ® nasal spray on the mucosal surfaces of the nasal cavity including but not limited to the location at which the medicament was retained and the amount and duration of retention.
- Twenty samples from the most recent available batches of Beconase AQ® nasal 15. spray.
- Twenty samples from batches of Beconase AQ® nasal spray based on the 16. formulation of Beconase AQ® nasal spray in effect on or before July 3, 1995.

AO 88 (Rev. 1/94) Subpoena in a Civil Case

# Issued by the UNITED STATES DISTRICT COURT

DISTRICT	OF NEW JERSEY	
AVENTIS PHARMACEUTICALS, INC. and SANOFI-AVENTIS US LLC		
V.	SUBPOENA IN A CIVIL CASE	
BARR LABORATORIES, INC.	CASE NUMBER: C.A. No. 06-286 (GMS) (For a case pending in the District of Delaware)	
TO: Custodian of Records Schering Corp. 2000 Galloping Hill Road Kenilworth, New Jersey 07033		
	strict Court at the place, date, and time specified below to testify in the	
above case. PLACE OF TESTIMONY	COURTROOM	
	DATE AND TIME	
YOU ARE COMMANDED to appear at the place, date, and case.	nime specified below to testify at the taking of a deposition in the above	
PLACE OF DEPOSITION	DATE AND TIME	
YOU ARE COMMANDED to produce and permit inspection time specified below (list documents or objects):	and copying of the following documents or objects at the place, date, and	
See Exhibit A attached	DATE AND TIME	
Schering Corp. 2000 Galloping Hill Road Kenilworth, New Jersey 07033	August 18, 2006 10:00 a.m.	
YOU ARE COMMANDED to permit inspection of the follow PREMISES	ving premises at the date and time specified below.  DATE AND TIME	
	f a deposition shall designate one or more officers, directors, or managing agents, each person designated, the matters on which the person will testify. Federal Rule	
ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENE	August 3, 2006	
Julia Mano		
Julia M. Mano, Attorney for Defendant Barr Laboratories, In	С.	
Julia M. Mano, Winston & Strawn LLP, 35 W. Wacker Dr., 0	Chicago, IL 60601 (312) 558-5600	

<sup>(</sup>See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

<sup>1</sup> If action is pending in district other than district of issuance, state district under case number.

AO 88 (Rev. 1/94) Subpoena in a	a Civil Case		
	PROOF OF SERVICE		
	DATE	PLACE	
SERVED			
SERVED ON (PRINT NAME)		MANN	ER OF SERVICE
SERVED BY (PRINT NAME)	(H-1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,		TITLE
		DECLARATIO	N OF SERVER
I declare under penathe Proof of Service is			States of America that the foregoing information contained in
Executed on		DATE	SIGNATURE OF SERVER
			_ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

- (c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.
- (1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.
- (2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.
- (B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.
- (3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
  - (i) fails to allow reasonable time for compliance;
  - (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in

person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

- (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
  - (iv) subjects a person to undue burden.
    - (B) If a subpoena
- (i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
- (ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
- (iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

## (d) DUTIES IN RESPONDING TO SUBPOENA.

- (1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.
- (2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

#### EXHIBIT A

## DEFINITIONS WITH RESPECT TO ITEMS SUBPOENAED

The terms used in the following list of items subpoenaed shall be construed as follows:

- "Schering" means "Schering Corp." and all of its predecessors, successors, parents, subsidiaries, affiliates, present and former directors, officers, employees, agents, representatives, investigators, attorneys, and all other persons acting or purporting to act for or on behalf of Schering involved in or related to the manufacture and/or sale of Vancenase AQ®.
  - "Documents" means documents as defined in Fed. R. Civ. P. 34(a)(1). B.
- "Relating to" means to consist of, refer to, reflect, or be in any way legally, C. logically, or factually connected with the matter discussed.
- When a document or thing that "concerns" or "concerning" any given matter is sought, the request encompasses any document or thing, as the case may be, containing, constituting, evidencing, referring to, discussing, or prepared in connection with the matter.

#### **INSTRUCTIONS**

- Each document or thing or group of documents or things produced in response to the subpoena shall indicate the item number of the subpoena to which it is responsive.
- В. For purposes of this subpoena, a document or thing is deemed to be in your control if you have the right to secure the document or thing or a copy thereof from another person or entity having actual possession of the document or thing.
- C. If a claim of privilege is asserted with respect to a document responsive to any of these requests, the following information shall be provided with respect to each such document:
  - the type of document, e.g., letter or memorandum; (a)
  - the general subject matter of the document; (b)
  - the date of the document; and (c)
  - such other information as is sufficient to identify the document for a (d) subpoena duces tecum, including, where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other.

#### ITEMS SUBPOENAED

- Documents, whether public or non-public, sufficient to identify, describe, or show 1. the formulation for Vancenase AQ® 0.042% nasal spray (NDA No. 019589) as of the approval date of NDA No. 019589, December 23, 1987, and any and all modifications to the Vancenase AQ® 0.042% formulation from December 23, 1987 to the present and the date of any such modification.
- 2. Documents, whether public or non-public, sufficient to identify, describe, or show the formulation for Vancenase AQ® 0.084% nasal spray (NDA No. 020469) as of the approval date of NDA No. 020469, June 26, 1996, and any and all modifications to the Vancenase AQ® 0.084% formulation from June 26, 1996 to the present and the date of any such modification.
- Documents, whether public or non-public, sufficient to identify, describe, or show the size of the solid particles of beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.042% nasal spray from December 23, 1987 to the present.
- Documents, whether public or non-public, sufficient to identify, describe, or show the size of the solid particles of beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.084% nasal spray from June 26, 1996 to the present.
- Twenty samples from the most recent available batches of Vancenase AO® 5. 0.042% nasal spray.
- Twenty samples from batches of Vancenase AQ® 0.042% nasal spray based on 6. the formulation of Vancenase AQ® 0.042% nasal spray in effect on or before July 3, 1995.
- Twenty samples from the most recent available batches of Vancenase AO® 0.084% nasal spray.
- Twenty samples from a batch of Vancenase AQ® 0.084% nasal spray based on the formulation of Vancenase AQ® 0.084% nasal spray in effect on or before June 26, 1996.
- Documents, whether public or non-public, concerning, referring to or relating to any and all nasal deposition pattern testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% including but not limited to the date of and results of such nasal deposition pattern testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all spray plume geometry testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray including but not limited to the date of and results of such spray plume geometry testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all viscosity testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray including but not limited to the date of and results of such viscosity testing.

Documents, whether public or non-public, concerning, referring to or relating to any and all testing performed to determine retention of the beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray on the mucosal surfaces of the nasal cavity including but not limited to the location at which the medicament was retained and the amount and duration of retention.

AO 88 (Rev. 1/94) Subpoena in a Civil Case

## Issued by the NITED STATES DISTRICT COU

DISTRICT OF NEW JERSEY			
AVENTIS PHARMACEUTICALS, INC. and SANOFI-AVENTIS US LLC	SUBPOENA IN A CIVIL CASE		
V.	SUBI OENA IN A CIVIL CASE		
BARR LABORATORIES, INC.	CASE NUMBER: C.A. No. 06-286 (GMS) (For a case pending in the District of Delaware)		
TO: Custodian of Records Schering Plough Corp. 2000 Galloping Hill Road Kenilworth, New Jersey 07033			
YOU ARE COMMANDED to appear in the United State above case.	ites District Court at the place, date, and time specified below to testify in the		
PLACE OF TESTIMONY	COURTROOM		
	DATE AND TIME		
YOU ARE COMMANDED to appear at the place, date case.	e, and time specified below to testify at the taking of a deposition in the above		
PLACE OF DEPOSITION	DATE AND TIME		
YOU ARE COMMANDED to produce and permit insp time specified below (list documents or objects):	pection and copying of the following documents or objects at the place, date, and		
See Exhibit A attached			
Schering Plough Corp. 2000 Galloping Hill Road Kenilworth, New Jersey 07033	DATE AND TIME August 18, 2006 10:00 a.m.		
	following premises at the date and time specified below.		
PREMISES	DATE AND TIME		
Any organization not a party to this suit that is subpoenaed for the to or other persons who consent to testify on its behalf, and may set for of Civil Procedure, 30(b)(6).	aking of a deposition shall designate one or more officers, directors, or managing agents, rth, for each person designated, the matters on which the person will testify. Federal Rules		
ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OF	August 3, 2006		
gulia mano			
Julia M. Mano, Attorney for Defendant Barr Laboratori	es, Inc.		
Julia M. Mano, Winston & Strawn LLP, 35 W. Wacker	Dr., Chicago, IL 60601 (312) 558-5600		

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

I If action is pending in district other than district of issuance, state district under case number.

AO 88 (Rev. 1/94) Subpoena in a Civil Case		
	PROOF OF	SERVICE
DATE	PLACE	
SERVED		
SERVED ON (PRINT NAME)	MANN	ER OF SERVICE
SERVED BY (PRINT NAME)		TITLE
	DECLARATIO	N OF SERVER
I declare under penalty of perjury the Proof of Service is true and correct		States of America that the foregoing information contained in
Executed on	DATE	SIGNATURE OF SERVER
		_ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

- (c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.
- (1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.
- (2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.
- (B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.
- (3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
  - (i) fails to allow reasonable time for compliance;
  - (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in

person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

- (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
- (iv) subjects a person to undue burden.
  - (B) If a subpoena
- (i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
- (ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
- (iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

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- (2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents. communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

## **DEFINITIONS WITH RESPECT TO ITEMS SUBPOENAED**

The terms used in the following list of items subpoenaed shall be construed as follows:

- A. "Schering Plough" means "Schering Plough Corp." and all of its predecessors, successors, parents, subsidiaries, affiliates, present and former directors, officers, employees, agents, representatives, investigators, attorneys, and all other persons acting or purporting to act for or on behalf of Schering involved in or related to the manufacture and/or sale of Vancenase AQ®.
  - B. "Documents" means documents as defined in Fed. R. Civ. P. 34(a)(1).
- C. "Relating to" means to consist of, refer to, reflect, or be in any way legally, logically, or factually connected with the matter discussed.
- D. When a document or thing that "concerns" or "concerning" any given matter is sought, the request encompasses any document or thing, as the case may be, containing, constituting, evidencing, referring to, discussing, or prepared in connection with the matter.

## **INSTRUCTIONS**

- A. Each document or thing or group of documents or things produced in response to the subpoena shall indicate the item number of the subpoena to which it is responsive.
- B. For purposes of this subpoena, a document or thing is deemed to be in your control if you have the right to secure the document or thing or a copy thereof from another person or entity having actual possession of the document or thing.
- C. If a claim of privilege is asserted with respect to a document responsive to any of these requests, the following information shall be provided with respect to each such document:
  - (a) the type of document, e.g., letter or memorandum;
  - (b) the general subject matter of the document;
  - (c) the date of the document; and
  - (d) such other information as is sufficient to identify the document for a subpoena duces tecum, including, where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other.

#### ITEMS SUBPOENAED

- Documents, whether public or non-public, sufficient to identify, describe, or show 1. the formulation for Vancenase AQ® 0.042% nasal spray (NDA No. 019589) as of the approval date of NDA No. 019589, December 23, 1987, and any and all modifications to the Vancenase AO® 0.042% formulation from December 23, 1987 to the present and the date of any such modification.
- 2. Documents, whether public or non-public, sufficient to identify, describe, or show the formulation for Vancenase AQ® 0.084% nasal spray (NDA No. 020469) as of the approval date of NDA No. 020469, June 26, 1996, and any and all modifications to the Vancenase AQ® 0.084% formulation from June 26, 1996 to the present and the date of any such modification.
- Documents, whether public or non-public, sufficient to identify, describe, or show the size of the solid particles of beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.042% nasal spray from December 23, 1987 to the present.
- Documents, whether public or non-public, sufficient to identify, describe, or show the size of the solid particles of beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.084% nasal spray from June 26, 1996 to the present.
- 5. Twenty samples from the most recent available batches of Vancenase AO® 0.042% nasal spray.
- Twenty samples from batches of Vancenase AQ® 0.042% nasal spray based on 6. the formulation of Vancenase AQ® 0.042% nasal spray in effect on or before July 3, 1995.
- Twenty samples from the most recent available batch of Vancenase AQ® 0.084% 7. nasal spray.
- Twenty samples from batches of Vancenase AQ® 0.084% nasal spray based on the formulation of Vancenase AQ® 0.084% nasal spray in effect on or before June 26, 1996.
- 9. Documents, whether public or non-public, concerning, referring to or relating to any and all nasal deposition pattern testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% including but not limited to the date of and results of such nasal deposition pattern testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all spray plume geometry testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray including but not limited to the date of and results of such spray plume geometry testing.
- Documents, whether public or non-public, concerning, referring to or relating to any and all viscosity testing performed using Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray including but not limited to the date of and results of such viscosity testing.

12. Documents, whether public or non-public, concerning, referring to or relating to any and all testing performed to determine retention of the beclomethasone dipropionate monohydrate medicament contained in Vancenase AQ® 0.042% and/or Vancenase AQ® 0.084% nasal spray on the mucosal surfaces of the nasal cavity including but not limited to the location at which the medicament was retained and the amount and duration of retention.

### CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on August 3, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

> Steven J. Balick, Esquire John G. Day, Esquire Tiffany Gever Lydon, Esquire **ASHBY & GEDDES** 222 Delaware Avenue, 17th Floor Wilmington, DE 19801

I further certify that on August 3, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following nonregistered participants in the manner indicated:

## **BY E-MAIL**

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